

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

IN RE NAMENDA DIRECT PURCHASER  
ANTITRUST LITIGATION

Case No. 1:15-cv-07488-CM (RWL)

**MEMORANDUM IN SUPPORT OF FOREST'S MOTION *IN LIMINE* 11  
TO PRECLUDE PLAINTIFFS FROM CONTRADICTING THEIR  
JUDICIAL ADMISSION THAT MEMANTINE IS AN NMDA ANTAGONIST**

**WHITE & CASE<sup>LLP</sup>**

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Forest Laboratories Holdings Ltd.*

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## I. INTRODUCTION

In assessing whether a brand pharmaceutical manufacturer entered into an unlawful agreement under the rubric of *FTC v. Actavis*, the Supreme Court directly implicated the strength or weakness of the brand's patent. 570 U.S. 136, 158 (2013) (so-called "reverse payments" may be unlawful if they are so "large" and "unjustified" as to permit the inference that they were made to eliminate the risk of a successful patent challenge). An important aspect of a patent's strength or "weakness" is whether it is likely that a defendant will be found to infringe. The patent at issue here is U.S. Patent No. 5,061,703 (the "'703 patent") which, as construed by the court in the underlying patent litigation, covers the treatment of a patient with Alzheimer's by way of an NMDA receptor antagonist.

Here, DPPs intend to offer the testimony of their proffered expert, Dr. Nathan Herrmann, to opine that Namenda IR's active ingredient memantine does not act as an NMDA receptor antagonist and therefore does not infringe the '703 patent. DPPs have already told this Court multiple times in their briefing on the relevant product market that memantine acts as an "NDMA [*sic*] antagonist," which is a judicial admission and the Court should preclude DPPs from making diametrically opposed arguments now. *See* ECF No. 136, Pls.' Mem. of Law in Support of Pls.' Mot. for Collateral Estoppel and Partial Summ. J. on Count One at 13 ("Pls.' Collateral Estoppel Mot."); *New Hampshire v. Maine*, 532 U.S. 742, 749 (2001) (citing *Pegram v. Herdrich*, 530 U.S. 211, 227 (2000)) (internal quotation marks omitted) ("This rule, known as judicial estoppel, generally prevents a party from prevailing in one phase of a case on an argument and then relying on a contradictory argument to prevail in another phase."); *Bates v. Long Island R.R.*, 997 F.2d 1028, 1037 (2nd. Cir. 1993) ("The doctrine of judicial estoppel prevents a party from asserting a factual position in a legal proceeding that is contrary to a

position previously taken by him in a prior legal proceeding.”).

Indeed, DPPs previously relied on the fact that memantine *was* an NMDA receptor antagonist in order to obtain a favorable ruling on the threshold issue of the relevant product market in this case. In their motion for collateral estoppel, DPPs argued that “Namenda IR and XR were the only two NDMA [*sic*] antagonists on the market,” and this Court held that Judge Sweet’s conclusion on product market has preclusive effect in the instant action. ECF No. 136, Pls.’ Collateral Estoppel Mot. at 13; *New York v. Actavis, PLC*, 2014 U.S. Dist. LEXIS 172918, at \*14, 44-45 (S.D.N.Y. Dec. 11, 2014) (*Namenda I*) (defining Namenda IR for purposes of product market as “an N-Methyl D-Aspartate (‘NMDA’) receptor antagonist”). DPPs cannot have it both ways, and they should be judicially estopped from making the opposite argument, that memantine does not act as an NMDA receptor antagonist, now. Therefore, the opinions of DPP’s expert, Dr. Herrmann, that Namenda (including any generic version thereof) does not act as an NMDA receptor antagonist in paragraphs 36–71 of his September 13, 2017 Expert Report are improper and should be precluded. The Court should also preclude Plaintiffs from offering any other evidence suggesting that memantine is not an NMDA receptor antagonist.

## II. ARGUMENT

### A. DPPs Should Be Judicially Estopped from Arguing that Memantine Is not an NMDA Receptor Antagonist

DPPs’ expert Dr. Herrmann has presented opinions that memantine does not act as an NMDA receptor antagonist both at deposition and in his expert report, despite these opinions being diametrically opposed to the representations DPPs have made to this Court. In his report, Dr. Herrmann opined that Namenda and Mylan’s generic memantine hydrochloride do “*not* provide therapeutic effects to Alzheimer’s disease patients by antagonizing NMDA receptors.” *See* Ex. 1, Expert Rep. of Nathan Herrmann (“Herrmann Rep.”) at ¶¶ 38, 71 (emphasis added).

Similarly, at deposition Dr. Herrmann testified that, “In my opinion, [Mylan’s expert in the underlying patent litigation] Dr. Olney presented several distinct, strong arguments that support the theory that memantine does not achieve therapeutic effect as an NMDA receptor antagonist at the proposed dosages in Mylan’s package insert.” *See* Ex. 2, Herrmann Dep. 60:21-61:11, 64:21-65:7, 74:4-75:3; Herrmann Rep., ¶ 54.

This framing amounts to a transparent attempt to avoid the high probability that Mylan would have been found to infringe the ’703 patent in the underlying patent litigation. Mylan’s own documents produced in the underlying patent litigation, including representations to the FDA, expressly state that Mylan’s generic memantine product was an NMDA receptor antagonist. Ex. 3, MYLMEMA\_001181 (“Memantine hydrochloride is an orally active NMDA receptor antagonist.”) (Mylan ANDA Module 1.14.2.3 Final Labeling Text). Yet DPPs now seek to exclude both Mylan’s generic product as well as Namenda itself from the very class of drugs to which this Court has already found they belong, based on DPPs’ argument. On one hand, DPPs argued that Namenda and generic memantine are in the NMDA product market where Forest has market power, a threshold prerequisite for all of DPPs’ allegations. On the other hand, DPPs seek to argue the flip side of the same coin, that Mylan’s generic memantine is not an NMDA receptor antagonist when it comes to the issue of infringement in the ’703 patent as part of the analysis under *FTC v. Actavis*.

In their motion for collateral estoppel and partial summary judgment, DPPs stated that “Namenda IR and XR were the only two NDMA [*sic*] antagonists on the market” and “Defendants were the only manufacturer of NDMA [*sic*] antagonists.” ECF No. 136, Pls.’ Collateral Estoppel Mot. at 13. In fact, DPPs dedicated an entire section of their brief to arguing that “The Relevant Market Is Brand and Generic *NMDA Antagonists*.” *Id.* at 11 (emphasis

added). Such statements should be considered judicial admissions, and therefore, DPPs should be precluded from now arguing the very opposite of these statements. *See Purge v. Sharrock*, 33 F.3d 134, 144 (2nd Cir. 1994) (“Counsel’s statement of fact constituted an admission of a party. It was made in a legal brief filed with the court subject to the penalty of sanctions.”); *Bellefonte Re Ins. Co. v. Argonaut Ins. Co.*, 757 F.2d 523, 529 (2nd Cir. 1985) (“A party’s assertion of fact in a pleading is a judicial admission by which it is normally bound throughout the course of the proceeding.”). Furthermore, in *Namenda I*, the government presented the testimony of numerous medical professionals, on whom the DPPs also relied in this case, who testified that memantine operated as an NMDA receptor antagonist. *See* Ex. 4, Declaration of James J. Lah, M.D., Ph.D., ¶ 7 (“Namenda works differently. It is an NMDA antagonist.”); Ex. 5, Declaration of Alan R. Jacobs, M.D., ¶ 24 (“Memantine, the active ingredient in Namenda®, is an NMDA receptor antagonist.”); Ex. 6, Declaration of Dr. Bruce D. Kohrman, M.D., ¶ 18 (“Memantine is an ‘NMDA receptor antagonist.’”); Ex. 7, Declaration of Barry Reisberg, M.D., ¶ 24 (“Namenda® is an NMDA (N-methyl-D-aspartate) receptor antagonist.”); Ex. 8, Declaration of Barry Rovner, M.D., ¶ 26 (“Current pharmacologic treatments for AD are the cholinesterase inhibitors [i.e., donepezil (Aricept), galantamine (Razadyne), and rivastigmine (Exelon)] and the NMDA receptor antagonist memantine (Namenda).”). DPP’s expert, Dr. Herrmann, even admitted that it is commonly understood that memantine acts as an NMDA receptor antagonist at deposition. *See, e.g.*, Ex. 2, Dep. of Nathan Herrmann (“Herrmann Dep.”) 60:15-20, 68:5-69:4 (“Q. [Y]ou would agree with me that that postulate [that memantine exerts its therapeutic effects through NMDA receptor antagonism] has been repeated many times in the scientific literature? A. It has.”).

Indeed, if DPPs are correct that memantine is not acting as an NMDA receptor

antagonist, then Namenda is not part of the product market relevant to this case, and there is no need to proceed to trial because Forest could not have acted anticompetitively in a market in which Namenda does not compete. *See Aquatherm Indus., Inc. v. Florida Power & Light Co.*, 145 F.3d 1258, 1262 fn.4 (11th Cir. 1998) (“[N]o authority exists holding a defendant can conspire to monopolize a market in which it does not compete.”); *Little Rock Cardiology Clinic, P.A. v. Baptist Health*, 573 F. Supp. 2d 1125, 1141 (E.D. Ark. Aug. 29, 2008) (“No one can monopolize a market if he does not produce the product or deliver the services constituting that market, which is to say that no one can monopolize a market in which he does not compete.”); *Moecker v. Honeywell Int’l, Inc.*, 144 F. Supp. 2d 1291 (M.D. Fla. Jan. 16, 2001) (“Where a defendant does not compete in a particular market it cannot be guilty of monopolization or attempted monopolization of a market in which it does not compete.”).

### III. CONCLUSION

For the foregoing reasons, Forest respectfully requests that this court preclude DPPs from offering testimony or argument that memantine does not act as an NMDA receptor antagonist.

Dated: May 24, 2019

Respectfully submitted,

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